

CLAIMS

1. A human growth hormone formulation comprising:
  - a) 1 mg/ml to 20 mg/ml human growth hormone,
  - b) buffer system providing pH 5.5 to pH 7,
  - 5 c) a tonicifying agent, and
  - d) an effective amount of Polyethylene glycol,  
in a sterile pharmaceutically acceptable liquid.
2. The human growth hormone formulation of claim 1 wherein the polyethylene glycol is PEG 1450 to PEG 20000.
- 10 3. The human growth hormone formulation of claim 2 wherein the polyethylene glycol is 5 mg/mL to 50 mg/mL.
4. The human growth hormone formulation of any one of claims 1 to 3 wherein said formulation is long term cold storage stable for 6 to 18 months at 2°C to 8°C.
- 15 5. The human growth hormone formulation of claim 4 including an antimicrobial agent.
6. The human growth hormone formulation of claim 5 wherein the polyethylene glycol is PEG 1450 to PEG 20000.
7. The human growth hormone formulation of claim 6 wherein the  
20 polyethylene glycol is 5 mg/mL to 50 mg/mL.
8. The human growth hormone formulation of claim 4 wherein the buffer system provides a pH 6.
9. The human growth hormone formulation of claim 8 wherein the tonicifying agent is mannitol.
- 25 10. The human growth hormone formulation of claim 4 including a chelating agent.
11. The human growth hormone formulation of claim 10 wherein the buffer system provides about pH 6.4.
12. The human growth hormone formulation of claim 11 including an  
30 antimicrobial agent.
13. A method for using human growth hormone comprising the steps of
  - A) formulating said human growth hormone into an aqueous liquid  
formulation comprising:

- a) 1 mg/ml to 20 mg/ml human growth hormone,
- b) buffer system providing pH 5.5 to pH 7,
- c) 5 mg/mL to 50 mg/mL polyethylene glycol, and
- d) a tonicifying agent,

5 in a pharmaceutically acceptable, injectable sterile aqueous vehicle,

B) storing said formulation as an aqueous liquid for from six to 18 months at 2°C to 8°C thereby forming a stored formulation; and

C) directly injecting said stored formulation into a patient in need of human growth hormone therapy.

10 14. A method for using human growth hormone comprising the steps of

A) formulating said human growth hormone into an aqueous liquid formulation consisting essentially of:

- a) 1 mg/ml to 20 mg/ml human growth hormone,
- b) buffer system providing pH 5.5 to pH 7,
- 15 c) 5 mg/mL to 50 mg/mL polyethylene glycol,
- d) 20 to 100 mg/mL of a tonicifying agent and
- e) an antimicrobial agent,

in a pharmaceutically acceptable, injectable sterile aqueous vehicle,

20 B) storing said formulation as an aqueous liquid for from six to 18 months at 2°C to 8°C thereby forming a stored formulation; and

C) directly injecting said stored formulation into a patient in need of human growth hormone therapy.

25 15. A method of making a storage stable aqueous formulation of human growth hormone comprising mixing said human growth hormone into an aqueous, pharmaceutically acceptable vehicle which comprises

- a) 1 mg/ml to 20 mg/ml of said human growth hormone;
- b) buffer providing pH 5.5 to pH 7;
- c) 5 mg/mL to 50 mg/mL polyethylene glycol; and
- d) 20 to 100 mg/mL of a tonicifying agent;

30 wherein said aqueous, pharmaceutically acceptable vehicle is capable of storage for 6 to 18 months at 2 to 8° C.